Application No.: 09/612,925

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [X] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

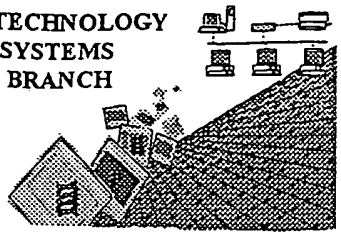
For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

1645

BIOTECHNOLOGY SYSTEMS BRANCH



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/612,925B
Source: 1600
Date Processed by STIC: 7/24/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) **INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
2) **TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
http://www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service:** U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. **Hand Carry directly to:**
   U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
   Or
   U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. **Federal Express, United Parcel Service, or other delivery service to:** U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION

SERIAL NUMBER: 09/612,925B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1_____Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2_____Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3_____Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4_____Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5_____Variable Length	Sequence(s)____contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6_____PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7_____Skipped Sequences (OLD RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
8_____Skipped Sequences (NEW RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9_____Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
10_____Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial-Sequence
11_____Use of <220>	Sequence(s) _____ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12_____PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13_____Misuse of n	n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

1645

RAW SEQUENCE LISTING DATE: 07/24/2002
PATENT APPLICATION: US/09/612,925B TIME: 14:24:11

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw

P4

<110> APPLICANT: Cano, Carlos Antonio Durante
Nieto, Enrique Gerardo Guillen
Acosta, Anabel Alvarez
Munoz, Luis Emilio Carpio
Vazquez, Diogenes Quintana
Rodriguez, Carmen Elena Gomez Rodriguez
Rodriguez, Recardo de la Caridad Siva
Galvez, Consuelo Nazabal
Angulo, Maria de Jesus Leal
Dunn, Alejandro Miguel Martin
<120> TITLE OF INVENTION: System for the Expression of Heterologous Antigens as Fusion Proteins
<130> FILE REFERENCE: LEXSA P-13DIV2
<140> CURRENT APPLICATION NUMBER: 09/612,925B
<141> CURRENT FILING DATE: 2000-07-10
<150> PRIOR APPLICATION NUMBER: 08/930,917
<151> PRIOR FILING DATE: 1997-09-16
<150> PRIOR APPLICATION NUMBER: CU97/00001
<151> PRIOR FILING DATE: 1997-01-17
<160> NUMBER OF SEQ ID NOS: 21
<170> SOFTWARE: PatentIn version 3.1
<210> SEQ ID NO: 1
<211> LENGTH: 47
<212> TYPE: PRT
<213> ORGANISM: Neisseria meningitidis
<400> SEQUENCE: 1

```
Met Leu Asp Lys Arg Met Ala Leu Val Glu Leu Lys Val Pro Asp Ile
1               5                  10                  15
Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
            20                  25                  30
Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Glu Thr Asp
        35                  40                  45
```

<210> SEQ ID NO: 2
<211> LENGTH: 18
<212> TYPE: PRT
<213> ORGANISM: Neisseria meningitidis
<400> SEQUENCE: 2

```
Thr Thr Cys Cys Ala Thr Gly Gly Thr Ala Gly Ala Thr Ala Ala Ala
1               5                  10                  15
Ala Gly
```

<210> SEQ ID NO: 3
<211> LENGTH: 18
<212> TYPE: PRT
<213> ORGANISM: Neisseria meningitidis

RAW SEQUENCE LISTING DATE: 07/24/2002
PATENT APPLICATION: US/09/612,925B TIME: 14:24:11

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw

```
70 <400> SEQUENCE: 3
72 Thr Thr Thr Cys Thr Ala Gly Ala Thr Cys Cys Ala Ala Ala Gly Thr
73 1               5                   10                  15
76 Ala Ala
80 <210> SEQ ID NO: 4
81 <211> LENGTH: 26
82 <212> TYPE: PRT
83 <213> ORGANISM: Neisseria meningitidis
85 <400> SEQUENCE: 4
87 Gly Gly Cys Gly Gly Thr Thr Cys Thr Gly Cys Cys Gly Ala Thr Thr
88 1               5                   10                  15
91 Ala Ala Gly Gly Ala Thr Cys Cys Gly Ala
92             20                  25
95 <210> SEQ ID NO: 5
96 <211> LENGTH: 146
97 <212> TYPE: PRT
98 <213> ORGANISM: Neisseria meningitidis
100 <400> SEQUENCE: 5
102 Thr Thr Cys Cys Ala Thr Gly Gly Thr Ala Gly Ala Thr Ala Ala Ala
103 1               5                   10                  15
106 Ala Gly Ala Ala Thr Gly Gly Cys Thr Thr Thr Ala Gly Thr Thr Gly
107             20                  25                  30
110 Ala Ala Thr Thr Gly Ala Ala Ala Gly Thr Gly Cys Cys Cys Gly Ala
111         35                  40                  45
114 Cys Ala Thr Thr Gly Gly Cys Gly Gly Ala Cys Ala Cys Gly Ala Ala
115     50                  55                  60
118 Ala Ala Thr Gly Thr Ala Gly Ala Thr Ala Thr Thr Ala Thr Cys Gly
119 65                  70                  75                  80
122 Cys Gly Gly Thr Thr Gly Ala Ala Gly Thr Ala Ala Ala Cys Gly Thr
123                 85                  90                  95
126 Gly Gly Gly Cys Gly Ala Cys Ala Cys Thr Ala Thr Thr Gly Cys Thr
127             100                 105                 110
130 Gly Thr Gly Gly Ala Cys Gly Ala Thr Ala Cys Cys Cys Thr Gly Ala
131         115                 120                 125
134 Thr Thr Ala Cys Thr Thr Thr Gly Gly Ala Thr Cys Thr Ala Gly Ala
135     130                 135                 140
138 Ala Ala
139 145
142 <210> SEQ ID NO: 6
143 <211> LENGTH: 47
144 <212> TYPE: PRT
145 <213> ORGANISM: Neisseria meningitidis
147 <400> SEQUENCE: 6
149 Met Val Asp Lys Arg Met Ala Leu Val Glu Leu Lys Val Pro Asp Ile
150 1               5                   10                  15
153 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
154             20                  25                  30
157 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Glu
158         35                  40                  45
```

<210> SEQ ID NO: 7
<211> LENGTH: 16
<212> TYPE: PRT
<213> ORGANISM: Neisseria meningitidis
<400> SEQUENCE: 7
Cys Thr Ala Gly Ala Thr Thr Thr Gly Ala Thr Ala Thr Cys Ala Gly
1 5 10 15
<210> SEQ ID NO: 8
<211> LENGTH: 16
<212> TYPE: PRT
<213> ORGANISM: Neisseria meningitidis
<400> SEQUENCE: 8
Gly Ala Thr Cys Cys Thr Gly Ala Thr Ala Thr Cys Ala Ala Ala Thr
1 5 10 15
<210> SEQ ID NO: 9
<211> LENGTH: 15
<212> TYPE: PRT
<213> ORGANISM: Human immunodeficiency virus type 1
<400> SEQUENCE: 9
Ser Arg Gly Ile Arg Ile Gly Pro Gly Arg Ala Ile Leu Ala Thr
1 5 10 15
<210> SEQ ID NO: 10
<211> LENGTH: 15
<212> TYPE: PRT
<213> ORGANISM: Human immunodeficiency virus type 1
<400> SEQUENCE: 10
Arg Gln Ser Thr Pro Ile Gly Leu Gly Gln Ala Leu Tyr Thr Thr
1 5 10 15
<210> SEQ ID NO: 11
<211> LENGTH: 15
<212> TYPE: PRT
<213> ORGANISM: Human immunodeficiency virus type 1
<400> SEQUENCE: 11
Arg Lys Ser Ile Thr Lys Gly Pro Gly Arg Val Ile Tyr Ala Thr
1 5 10 15
<210> SEQ ID NO: 12
<211> LENGTH: 15
<212> TYPE: PRT
<213> ORGANISM: Human immunodeficiency virus type 1
<400> SEQUENCE: 12
Arg Lys Arg Ile His Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr
1 5 10 15
<210> SEQ ID NO: 13
<211> LENGTH: 15
<212> TYPE: PRT
<213> ORGANISM: Human immunodeficiency virus type 1
<400> SEQUENCE: 13
Arg Lys Arg Ile Thr Met Gly Pro Gly Arg Val Tyr Tyr Thr Thr
1 5 10 15

RAW SEQUENCE LISTING DATE: 07/24/2002
PATENT APPLICATION: US/09/612,925B TIME: 14:24:11

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw

```
238 <210> SEQ ID NO: 14
239 <211> LENGTH: 15
240 <212> TYPE: PRT
241 <213> ORGANISM: Human immunodeficiency virus type 1
243 <400> SEQUENCE: 14
245 Ser Ile Arg Ile Gln Arg Gly Pro Gly Arg Ala Phe Val Thr Ile
246 1               5                   10                  15
249 <210> SEQ ID NO: 15
250 <211> LENGTH: 15
251 <212> TYPE: PRT
252 <213> ORGANISM: Human immunodeficiency virus type 1
254 <400> SEQUENCE: 15
256 Thr Ser Ile Thr Ile Gly Pro Gly Gln Val Phe Tyr Arg Thr Gly
257 1               5                   10                  15
260 <210> SEQ ID NO: 16
261 <211> LENGTH: 15
262 <212> TYPE: PRT
263 <213> ORGANISM: Human immunodeficiency virus type 1
265 <400> SEQUENCE: 16
267 Arg Gln Arg Thr Ser Ile Gly Gln Gly Gln Ala Leu Tyr Thr Thr
268 1               5                   10                  15
271 <210> SEQ ID NO: 17
272 <211> LENGTH: 5
273 <212> TYPE: PRT
274 <213> ORGANISM: unidentified
276 <400> SEQUENCE: 17
278 Ala Gly Gly Gly Ala
279 1               5
282 <210> SEQ ID NO: 18
283 <211> LENGTH: 141
284 <212> TYPE: PRT
285 <213> ORGANISM: Human immunodeficiency virus type 1
287 <400> SEQUENCE: 18
289 Cys Ala Pro Thr Ser Ser Ser Thr Ala Gln Thr Gln Leu Gln Leu Glu
290 1               5                   10                  15
293 His Leu Leu Leu Asp Leu Gln Ile Phe Leu Ser Arg Gly Ile Arg Ile
294             20                  25                  30
297 Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly Gly Gly Ala Arg Gln
298         35                  40                  45
301 Ser Thr Pro Ile Gly Leu Gly Gly Ala Leu Tyr Thr Thr Ala Gly Gly
302     50                  55                  60
305 Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly Arg Val Ile Tyr Ala
306 65                  70                  75                  80
309 Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His Ile Gly Pro Gly Arg
310                 85                  90                  95
313 Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile Thr Met
314             100                 105                 110
317 Gly Pro Gly Arg Val Tyr Tyr Thr Thr Ala Gly Gly Gly Ala Ser Ile
318         115                 120                 125
```

invalid response - see item 10 on Error Summary Sheet

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/612,925B

DATE: 07/24/2002
TIME: 14:24:11

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw

```
321 Arg Ile Gln Arg Gly Pro Gly Arg Ala Phe Val Thr Ile
322     130                 135                 140
325 <210> SEQ ID NO: 19
326 <211> LENGTH: 162
327 <212> TYPE: PRT
328 <213> ORGANISM: Human immunodeficiency virus type 1
330 <400> SEQUENCE: 19
332 Met Val Asp Lys Arg Met Ala Leu Val Glu Leu Lys Val Pro Asp Ile
333 1               5                   10                  15
336 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
337             20                  25                  30
340 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Asp Ser
341         35                  40                  45
344 Arg Gly Ile Arg Ile Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly
345     50                  55                  60
348 Gly Gly Ala Arg Gln Ser Thr Pro Ile Gly Leu Gly Gly Ala Leu Tyr
349 65                  70                  75                  80
352 Thr Thr Ala Gly Gly Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly
353                 85                  90                  95
356 Arg Val Ile Tyr Ala Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His
357             100                 105                 110
360 Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg
361         115                 120                 125
364 Lys Arg Ile Thr Met Gly Pro Gly Arg Val Tyr Tyr Thr Thr Ala Gly
365     130                 135                 140
368 Gly Gly Ala Ser Ile Arg Ile Gln Arg Gly Pro Gly Arg Ala Phe Val
369 145                 150                 155                 160
372 Thr Ile
376 <210> SEQ ID NO: 20
377 <211> LENGTH: 202
378 <212> TYPE: PRT
379 <213> ORGANISM: Human immunodeficiency virus type 1
381 <400> SEQUENCE: 20
383 Met Val Asp Lys Arg Met Ala Leu Val Glu Leu Lys Val Pro Asp Ile
384 1               5                   10                  15
387 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
388             20                  25                  30
391 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Asp Ser
392         35                  40                  45
395 Arg Gly Ile Arg Ile Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly
396     50                  55                  60
399 Gly Gly Ala Arg Gln Ser Thr Pro Ile Gly Leu Gly Gln Ala Leu Tyr
400 65                  70                  75                  80
403 Thr Thr Ala Gly Gly Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly
404                 85                  90                  95
407 Arg Val Ile Tyr Ala Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His
408             100                 105                 110
411 Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg
412         115                 120                 125
```

VERIFICATION SUMMARY
PATENT APPLICATION: US/09/612,925B

DATE: 07/24/2002
TIME: 14:24:12

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw